

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729:8-3-04

Rule Type: New

Rule Title/Tagline: Frequency requirements for submitting drug database information.

Agency Name: State Board of Pharmacy

Division:

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I. Rule Summary

1. **Is this a five year rule review?** No
 - A. **What is the rule's five year review date?**
2. **Is this rule the result of recent legislation?** No
3. **What statute is this rule being promulgated under?** 119.03
4. **What statute(s) grant rule writing authority?** 3719.28, 4729.26, 4729.84
5. **What statute(s) does the rule implement or amplify?** 4729.84, 4729.75, 4729.76, 4729.77, 4729.78, 4729.79, 4729.80, 4729.81, 4729.82, 4729.83
6. **What are the reasons for proposing the rule?**

This rule is necessary to promote the public's safety and uniformity of care throughout Ohio. Without this regulation, the State of Ohio Board of Pharmacy would not be able to provide uniform requirements for the operation of the Ohio Automated Rx Reporting System as required by ORC 4729.84.
7. **Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.**

Provides the frequency of when sales data must be transmitted to OARRS. Requires a reporting prescriber or pharmacy to submit their business hours electronically. It also requires notification if a prescriber or pharmacy no longer submits data to OARRS.

8. **Does the rule incorporate material by reference? Yes**
9. **If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.71 to 121.76, please explain the basis for the exemption and how an individual can find the referenced material.**
This rule references the Ohio Administrative Code. The O.A.C. is generally available in libraries and on the internet to persons who reasonably can be expected to be affected by the rule.
10. **If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

Not Applicable

II. Fiscal Analysis

11. **As a result of this proposed rule, please estimate the increase / decrease in revenues or expenditures affecting this agency, or the state generally, in the current biennium or future years. If the proposed rule is likely to have a different fiscal effect in future years, please describe the expected difference and operation.**

This will have no impact on revenues or expenditures.

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Not applicable.

12. **What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?**

Provides the frequency of when sales data must be transmitted to OARRS. Requires a reporting prescriber or pharmacy to submit their business hours electronically. It also requires notification if a prescriber or pharmacy no longer submits data to OARRS. The notification requirements listed in the rule will result in administrative costs to pharmacies and prescribers that dispense controlled substances and gabapentin. This burden is lessened in that there is online form that can be submitted from the OARRS interface. Submission of the form takes approximately 5 minutes.

13. **Does the rule increase local government costs? (If yes, you must complete an RSFA Part B). No**
14. **Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C). No**

III. Common Sense Initiative (CSI) Questions

15. **Was this rule filed with the Common Sense Initiative Office? Yes**
16. **Does this rule have an adverse impact on business? Yes**

- A. **Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business? No**
- B. **Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms? Yes**

Violation of this rule may result in administrative discipline for a licensee. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine and/or revocation of a license.

- C. **Does this rule require specific expenditures or the report of information as a condition of compliance? Yes**

Requires drug sales data as a condition of compliance.